

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-6, 9, 11, 20-21, 28-33, 38-55, 59, 61-63 and 68-70 are pending. Claims 37 and 60 are canceled without prejudice to future prosecution of that subject matter. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for variant antibodies selected by affinity maturation may be found, inter alia, at pages 18, lines 21-22; page 28, lines 18-19; and page 29, lines 3-5, of the specification.

Applicants request rejoinder of withdrawn claims 2-3 and 5-6 as they are directed to the elected invention. Independent claim 1 is allowed. Claims 2-3 and 5-6 contain all limitations of claim 1 (i.e., the elected invention) because of their claim dependencies.

In the alternative, claim 1 is a generic or linking claim that links the species represented by claims 2-3 and 5-6. Claim 1 recites an antibody having the CDR sequences shown in SEQ ID NOS: 24-26 and 33-35, and variants thereof. The CDR3 sequences set forth in claims 2-3 and 5-6 are all affinity matured variants of the CDR3 sequence shown in SEQ ID NO: 26. Claims are not required to further limit all six elected CDRs to be rejoined because claims 2-3 depend from claim 1 and they further limit the heavy chain CDR3 region of claim 1(iii)(a). Claims 2-3 and 5-6 are amended to specify amino acid sequences for an affinity matured variant of SEQ ID NO: 26. Claims 2-3 and 5-6 therefore read on all six of the CDR regions specified in claim 1(iii)(a)-(f). Rejoinder of withdrawn claims 2-3 and 5-6 in this application is therefore requested.

Further, in accordance with the Commissioner's Notice of March 26, 1996 (1184 OG 86) implementing the Federal Circuit's decisions of *In re Ochiai*, 37 USPQ2d 1127 (1995) and *In re Brouwer*, 37 USPQ2d 1663 (1996), Applicants request rejoinder of the withdrawn claims 61-63 and 69 because the claimed methods comprise the use of the antibody or antibody fragment of allowed product claim 1.

Claim Objections

The Examiner objected to claim 4 for being dependent upon a withdrawn claim. Claim 4 is amended to depend from claim 1. Therefore, claim 4 is in proper dependent form and withdrawal of the objection to claim 4 is requested.

She also objected to claims 38-39 and 41 as dependent on a rejected base claim (i.e., claim 37). The limitations of claim 37 are incorporated into claim 38; claim 40 is amended to depend from amended claim 38. Therefore, claim 38 is in independent form and claims 39-41 are in proper dependent form. Withdrawal of the objection to claims 38-39 and 41 is requested.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 37 and 40 were rejected under 35 USC 112, first paragraph, as allegedly lacking enablement. Applicants traverse.

The rejection of claim 37 is mooted by its cancellation. Claim 40 is amended to depend from claim 38, which recites an antibody comprising three heavy chain and three light chain CDRs. Therefore, withdrawal of the enablement rejection is requested.

Claim 60 was rejected under 35 USC 112, first paragraph, as allegedly lacking enablement. Applicants traverse because cancellation of the claim renders this rejection moot. Withdrawal of the rejection is requested.

Claim 9 was rejected under 35 USC 112, first paragraph, as allegedly failing to comply with the enablement requirement. Applicants traverse because the amendment to recite “wherein said polypeptide having the amino acid sequence of a part of SEQ ID

NO: 1 comprises the sequence shown in SEQ ID NO: 5” is supported by the results in the working examples of the present specification.

Applicants’ specification teaches that antibody 807A-M0028-B02 having the six CDR sequences recited in claim 1 specifically binds to the peptide of SEQ ID NO: 5. Table 22 at pages 124-125 of the specification shows that 807A-M0028-B02 binds to peptide 4 (see the first line of the Table on page 125, column 5). Peptide 4 has the sequence shown in SEQ ID NO: 5 (see page 9, lines 15-16 of the specification). Table 8 at page 94 of the specification discloses that 807A-M0028-B02 has the heavy chain CDR sequences shown in SEQ ID NOS: 24 to 26 and the light chain CDR sequences shown in SEQ ID NOS: 33 to 35 (see second line of Table). Therefore, the present specification enables the skilled artisan to make and use the claimed invention wherein antibodies according to claim 1 specifically bind peptides of claim 9 (i.e., comprising SEQ ID NO: 5). Withdrawal of the enablement rejection is requested.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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